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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,258	12/04/2003	James Boll	CYNO-16	7798

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EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,258	BOLL ET AL.	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 24-37* is/are rejected.

7)☒ Claim(s) *22 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/4/03* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

This application lacks formal drawings. The informal drawings filed in this application are marginally acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: # 14, # 84 & # 9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "40" has been used to designate both the scope and endoscope; also reference character "112" has been used to designate both a catheter scope and a microcatheter. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The label "W" is shown as two different elements in Figures 1A and 1B.

On page 21, a balloon # 38 is indicated in figure 4. There is no 38 in figure 4.

Page 27 lists a figure 16. There is no figure 16.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The cooling of the fluid of claim 3 is not cited in the specification.

The disclosure is objected to because of the following informalities:

On page 1, the title is incomplete.

The applicant uses endoscope and scope in an inconsistent manner. If the term scope is intended to be for visualization as is implied, it is suggested the term visualization port or other art accepted term be used.

The term "scope sheath annulus" on page 5 is not clearly defined.

The term sheath is used in a manner consistent with an introducer or cannula, rather than a traditional manner defining a protection of cover of an endoscope or catheter.

The text at the beginning of page 9 does not seem to logically follow that on page 8.

The phrase "around 30 + or – thirty " on page 9 (also page 24) is not clear.

On page 20 an inflated balloon as is figure 1A is cited and is inconsistent with that figure.

On page 24, the laser is indicated as having 8.0 Joules available. The rating as energy is improper as energy is a function of power over time.

On page 24, the term "visualization in a more proper manner is not understood.

On page 25, the word optimum is misspelled.

The paragraph regarding beam deflection on page 25 is not clear. No means is shown in figure 9 to deflect the beam or control the convergence.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no disclosure or drawing disclosing a structure or process by which a biodegradable occlusion device would be included in the device.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is improperly dependent on a method claim.

Claim 33 recites the limitation "biodegradable or digestable material" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 recites the limitation "bioasorbable or digestable material" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 9-15, 17-20, 34 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,755,849 to Gowda et al. Gowda et al. disclose a method for delivering energy to a tissue. The method includes providing an apparatus which includes an energy delivery component and an inflatable member disposed around the energy delivery component (abstract). The method may be used to treat Barrett's esophagus (Col. 1, line 33). The thermal delivery apparatus is inserted into an esophagus under local anesthesia and positioned under endoscopic (use with an endoscope) guidance at the level of lower esophageal sphincter. Once at the desired position, inflatable member is inflated such that inflatable member engages the walls of esophagus. Optical energy (e.g., laser light) is then delivered through optical delivery component (Fig. 3A, # 46, note it is within the balloon). The invention can be practiced using a thermal delivery apparatus configured such that optical energy is delivered to only a portion of the LES. Optical delivery component can then be made

to mechanically (articulate) scan the tissue to create a homogenous lesion along any desired length of the LES. Such mechanical scanning can be carried out, for example, by moving optical delivery component axially relative to central lumen of the tubular housing or by deflating inflatable member, moving thermal delivery apparatus relative to LES, and repeating the procedure (Col. 10, lines 4-31). The cooling fluid may be saline (Col. 11, line 31). The endoscope (Fig. 2A, # 42) is within the balloon (Fig. 2A, # 44). It is inherent the balloon is optically transparent as the energy delivery component passes through the inflatable member's inner wall, through the cooling fluid disposed in the cavity, through the inflatable member's outer wall, and into the tissue (Col. 9, lines 1-10). The use of multiple optical fibers for delivery of the laser energy is also disclosed (Col. 7, lines 16-20).

Claims 24-27, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,409483 to Campbell et al. Campbell et al. teach a surgical probe for use in a hollow vessel or other region of the body which comprises a multi-lumen catheter having a transparent, non-compliant balloon coupled to the distal end, such that the balloon has a known shape when inflated. A direct visualization scope is provided in a first lumen of the multi-lumen catheter providing direct visualization into the hollow vessel through the non-compliant balloon (abstract). An inflation lumen and a deflation lumen are disclosed implying a means for inflation and deflation of the balloon (Col. 7, lines 60-61). A fiber optic is provided in a third lumen of the multi-lumen catheter to deliver light energy to the hollow vessel through the non-compliant balloon, which may be configured with a cylindrical section or other desired shape. Within the balloon, a mechanism is provided for positioning the light emitting tip of the fiber optic within the balloon (Col. 3, lines 47-54). The fiber may emit the light from a side (Fig. 3). Campbell et al. teach the use of the device with a sheath and a cannula (Col. 14, lines 13-15). In the art, the use of endoscopes and catheters with sheaths, cannulae and introducers is common, blurring

the definitions of each. The disclosure by Campbell et al. of a sheath and cannula with multiple lumens for support is interpreted as the supporting sheath of claim 26.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,755,849 to Gowda et al. as applied to claims 1 and 2 above and further in view of U.S. Patent Application Publication US 2003/0060813 to Loeb et al. Gowda et al. are discussed above, bit do not disclose scattering of the light energy within the fluid. Loeb et al. teach a device for applying radiant energy to tissue surrounding or underlying the surface of a duct, hollow organ or body cavity. The energy is emitted through an expandable, energy-transmissive balloon in which a fluid coolant is circulated to cool the surface of the duct, hollow organ or body cavity and the tissue immediately underlying the surface of the duct, hollow organ or body cavity. The device includes an elongated transmission line extending through a catheter, having a proximal

end portion, which is connectable to a source of radiant energy, and a distal end portion, to which a radiant energy emitter is coupled. The balloon is mounted on the distal end of the catheter and extends over the emitter. The catheter contains an inlet confined fluid passageway and an outlet confined fluid passageway to provide fluid coolant circulation through the balloon. Microscopic albumen microspheres or particles of quartz or silica are suspended in the fluid coolant to more uniformly diffuse the radiant energy (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the diffusive fluid as taught by Loeb et al. in the method of Gowda et al. to control the light energy in a uniform manner as is known in the art.

Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,755,849 to Gowda et al. as applied to claim 1 above and further in view of U.S. Patent 5,409,483 to Campbell et al. Gowda et al. are discussed above, bit do not disclose a visualization capability or positionable fiber. Campbell et al. teach a surgical probe for use in a hollow vessel or other region of the body which comprises a multi-lumen catheter having a transparent, non-compliant balloon coupled to the distal end, such that the balloon has a known shape when inflated. A direct visualization scope is provided in a first lumen of the multi-lumen catheter providing direct visualization into the hollow vessel through the non-compliant balloon (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the visualization as taught by Campbell et al. in the device of Gowda et al. as such visualization is well known and pervasive in the art for remote invasive procedures.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,755,849 to Gowda et al. as applied to claim 1 above and further in view of U.S. Patent Application Publication US 2004/0249243 to Kleiner. Gowda et al. are discussed above, but do

not disclose a window at the distal end of the balloon. Kleiner teaches a device for use in a body cavity with an expandable balloon that includes a window portion on the distal end (paragraph 0086) for visualization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the window as taught by Kleiner in the device of Gowda et al. to provide visual guidance for the proper positioning of the device.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,409,483 to Campbell et al. as applied to claim 24 above and further in view of U.S. Patent 5,558,667 to Yarborough et al. Campbell et al. are discussed above but do not disclose specific laser parameters. Lasers are well known in the medical art and are available with wide ranges of operating parameters. Yarborough et al. disclose such a medical laser using an Nd:YAG laser to produce a wavelength of 532 nanometers (Col. 3. line 19) with a pulse duration of from 0.5 to 10 ms (Col. 3, line 38) and repetition rates greater than 1 KHz (Col. 5, lines 19-20). Fluences from 0.5 to 3 Joules are disclosed (Col. 4, line 14). The actual fluence delivered is well known to be a function several parameters so the device is capable of virtually any fluence depending on the pulse width, repetition rate, power and treatment time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a laser as suggested by Yarborough et al. in the invention of Campbell et al. as it provides the treatment capabilities required to treat the lesions and is easily delivered via an optical fiber.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,409,483 to Campbell et al. as applied to claim 24 above and further in view of U.S. Patent Application Publication US 2003/0060813 to Loeb et al. Campbell et al. are discussed above, but do not disclose the use of radiopaque markers. Loeb et al. disclose the use of radiopaque substances on a medical device for use in fluoroscopy (paragraph 0108). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the

radiopaque substance as taught by Loeb et al. in the invention of Campbell et al. as the use of such markings is well known and pervasive in the art to provide positional information to the clinical operator.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,409,483 to Campbell et al. as applied to claim 30 above and further in view of U.S. Patent 6,635,068 to Dubrul et al. Campbell et al. are discussed above, but do not teach an umbrella occlusion device. Dubrul et al. teach the shape of an expanding occlusion mechanism may be varied and includes, but is not limited to an umbrella shape, a spheroid shape, an ovoid shape, a conical shape, a disc-shape, etc. (Col. 3, lines 25-30), thus teaching the functional equivalency of a balloon and umbrella configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the umbrella as taught by Dubrul et al. in the invention of Campbell et al. as an alternative equivalent to the balloon occlusion member.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,409,483 to Campbell et al. as applied to claim 30 above and further in view of U.S. Patent 6,792,979 to Konya et al. Campbell et al. are discussed above, but do not teach a biodegradable occlusion device. Konya et al. teach stents, occluders and filters made of a biodegradable woven material (Col. 32, lines 17-21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the biodegradable occlusion element as taught by Konya et al. in the invention of Campbell et al. as an alternative to the expandable balloon for occluding the esophagus.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,755,849 to Gowda et al. as applied to claim 34 above and further in view of U.S. Patent 6,635,068 to Dubrul et al. Gowda et al. are discussed above, but do not teach an umbrella

occlusion device. Dubrul et al. teach the shape of an expanding occlusion mechanism may be varied and includes, but is not limited to an umbrella shape, a spheroid shape, an ovoid shape, a conical shape, a disc-shape, etc. (Col. 3, lines 25-30), thus teaching the functional equivalency of a balloon and umbrella configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the umbrella as taught by Dubrul et al. in the invention of Gowda et al. as an alternative equivalent to the balloon occlusion member.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,755,849 to Gowda et al. as applied to claim 34 above and further in view of U.S. Patent 6,792,979 to Konya et al. Gowda et al. are discussed above, but do not teach a biodegradable occlusion device. Konya et al. teach stents, occluders and filters made of a biodegradable woven material (Col. 32, lines 17-21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the biodegradable occlusion element as taught by Konya et al. in the invention of Gowda et al. as an alternative to the expandable balloon for occluding the esophagus.

Allowable Subject Matter

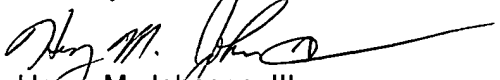
Claims 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
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